K070338

AUG 2 8 2007

510(k) _____

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Federal Food, Drug, and Cosmetic Act.

Date Prepared: February 1, 2007

CFR 807.92(a)(1), Submitter's Information:

Sean Zhang
President & CTO
Rainbow Communications, Inc.
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U.S.A.
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21 CFR 807.92(a)(2), Trade Name, Common Name & Classification:

Trade Name:	Rainbow™, Rainbow Light™, Rainbow Blue™, Rainbow Plus™
Common Name:	Portable LED Phototherapy Device
Regulation:	21 CFR 890.5500
Classification Name:	Infrared Lamp
Device Classification:	II
Product Code (Primary):	ILY

21 CFR 807.92(a)(3), Predicate Device:

Rainbow™, Rainbow Light™, Rainbow Blue™, or Rainbow Plus™ Portable LED Phototherapy Device (*herein after as* "the device") is substantially equivalent to the following identified devices:

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Rainbow Communications, Inc.
% Dahyee Law Group, P.C.
Mr. Leon E. Jew
24301 Southland Drive, Suite 405
Hayward, California 94545

Re: K070338
Trade/Device Name: RAINBOW LIGHT™, Portable LED Phototherapy Devices
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: June 29, 2007
Received: July 2, 2007

Dear Mr. Jew:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K070338

Device Name: Rainbow™, Rainbow Light™, Rainbow Blue™, Rainbow Plus™ Portable LED Phototherapy Devices

Indications for Use:

Rainbow™, Rainbow Light™, Rainbow Blue™, Rainbow Plus™ Portable LED Phototherapy Devices are for an ordinary person's home-use without additional assistance from professionals to emit light energy to the body and skin for the purpose of for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm, relieving stiffness, promoting relaxation of muscle tissue, and temporarily increasing local blood circulation where light is applied.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070338